From: **Cynthia Caporale/ESC/R3/USEPA/US**
Sent: 3/15/2012 3:44:18 PM

To: Ex. 4 - CBI
CC: Ex. 4 - CBI Gary Newhart/CI/USEPA/US@EPA; John Gilbert/CI/USEPA/US@EPA; Kelley Chase/R3/USEPA/US@EPA; Ex. 4 - CBI Robin Costas/ESC/R3/USEPA/US@EPA; Dave Russell/ESC/R3/USEPA/US@EPA
Subject: Re: Verification/Completeness Checks for Dimock (Micro Weeks 3 and 4 Posted Mar 08)

Kelley and Ex. 4 - CBI

Dave reviewed the Dimock Verification/Completeness Check report for NEL Weeks 3 and 4. Below are the responses for your consideration.

Regarding 031412-25 --- #1:

Don't agree with this statement: "There is no criterion to qualify samples based on field blank or lab blank contamination." This is puzzling because certainly there is a requirement to qualify data based on whether or not the lab followed the method. Running a lab blank with each set of samples is part of the method, therefore the absence of a lab blank would be an acceptable basis for qualifying data. In the validation report the term "method blank" was used for lab blank.

Agree with some but not all of this statement: "Since all data has been qualified unusable (R) based on the absence of both negative and positive controls, no further qualifications are necessary."

I agree that since all the HPC data was qualified unusable, qualifying some or all of it on other bases is unnecessary. The phrase "based on the absence of both negative and positive controls" needs to be corrected. A "negative control" is not the same thing as a "lab blank" (or sterility control). A "negative control" involves inoculation of the medium (agar or broth) with a species that is known not to grow in that medium, and a "lab control" (aka "sterility control" or "method blank") involves adding either nothing or sterile water to the medium in order to assess conditions and analyst technique during performance of the method at the bench--- to determine whether they could have contaminated test samples during analysis. Thus, it is not correct to use "negative control" to refer to a lab blank.

Furthermore, the Microbiology Data Validation Report for Week 3 indicates that the qualification of HPC data as unusable was based only on the absence of a lab blank (=sterility blank or method blank). The HPC data was not qualified as unusable on the basis of the missing positive control. Why? Because the absence of a positive control for HPC is much less serious compared to the absence of a sterility control (or lab blank). The fact that some sample plates showed CFU growth demonstrates that the agar could support growth, making the absence of a positive control less critical, and therefore, it was not considered a basis for rejecting the data, but just qualifying it as biased low. (A positive control is still important, however, and should have been performed when the agar batch was prepared -- as required by EPA's SDWA Lab Cert Manual.)

The statement above should read: "Since all data has been qualified unusable (R) based on the absence of method blanks, no further qualifications are necessary."

Regarding 031412-25 --- #2:

As explained above "both negative and positive controls" should be changed to "method blanks".

Yes, an updated lab report for HW51 should be requested.

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Ex. 4 - CBI
Date: 03/15/2012 12:01 PM
Subject: Verification/Completeness Checks for Dimock (Micro Weeks 3 and 4 Posted Mar 08)

.....are attached for your review and consideration.

Ex. 4 - CBI
Lockheed Martin
Scientific, Engineering, Response and Analytical Services (SERAS)

Ex. 4 - CBI

[attachment "SERAS-172-DSR-031412_25.docx" deleted by Cynthia Caporale/ESC/R3/USEPA/US] [attachment "SERAS-172-DSR-031512_26.docx" deleted by Cynthia Caporale/ESC/R3/USEPA/US]